THE ONGOING CHALLENGES OF CATEGORY I UV FILTERS AND FDA

The movement toward the total elimination of oxybenzone and octinoxate as Category I UV filters continues. The latest developments include a bill introduced in the US House of Representatives on July 1 by Francis Rooney (R-FL) and Debbie Mucarsel-Powell (D-FL) requesting that the US Commerce Department "issue regulations prohibiting the use of sunscreens containing oxybenzone or octinoxate in a National Marine Sanctuary in which coral is present, and for other purposes."[1] Additionally, the US Virgin Islands is moving to ban these filters like Hawaii and Key West, FL. Bill 33-0043 is expected to be signed in July by Gov. Albert Bryan. Additionally, Harith Wickerman, president of the Island Green Living Association, declared that "Oxybenzone, octinoxate and octocrylene devastate coral and marine life and are also known carcinogenic and hormone disruptors in humans."[2]

Such devastating statements, not yet proven, are obviously emboldened by the FDA's recent publication in the Journal of American Medical Association (JAMA) showing that UV filters have been found in the blood of human volunteers at much higher levels than deemed safe."[3]

Sunscreen ingredients are blamed for damaging coral reefs.

In addition, the FDA's new proposed recommendations, published in February, designated 12 UV filters as Category III ingredients requiring extensive Maximal Usage Testing (MUsT) and Development and Reproductive Toxicity (DART) testing before they can be deemed Generally Regarded as Safe and Effective (GRASE) items and reclassified as Category I ingredients again. The FDA proposal and publication of the JAMA report have created havoc and upheaval in the industry by populating the internet with doom and gloom reports on the safety of US sunscreens in general. It has also prompted Senator Chuck Schumer (D-NY) to request that the FDA scrutinize chemicals in sunscreens that "seep into the bloodstream."[4]

In a letter to US Secretary of Health and Human Services Alex Azar in June, Senators Johnny Isakson (R-GA), Lamar Alexander (R-TN) and Richard Burr (R-NC) asked the Administration to help Americans better understand the recent report from the FDA regarding the safety and effectiveness of sunscreen products available in the US.[5]

FDA Acting Commissioner Norman Sharpless, MD, responded by assuring the Senators that the FDA has taken numerous steps to establish, reinforce and spread more widely the messages that consumers should continue to use their sunscreens. As to the status of the 12 pending UV filters that the FDA has deemed non-GRASE Category III ingredients, Sharpless stated that the FDA will allow manufacturers of those 12 UV filters to request "deferrals." A deferral means the FDA does not intend to issue a final rule on the ingredients in question until the sponsors have had sufficient time to conduct the necessary studies suggested. If a sunscreen ingredient is deferred, the FDA anticipates that products containing the ingredient will remain on the market while the data is gathered for that filter. Of course, those products will remain in the market under the specter and shadow of the FDA's February ruling that those 12 ingredients are no longer considered Category I GRASE filters.

Nadim Shaath
Alpha Research & Development Ltd
Email: alphamd@aol.com

Dr. Nadim Shaath is the president of Alpha Research & Development, Ltd. in White Plains, NY. He has over 30 years of experience as chairman of the chemistry department at SUNY-Purchase and the CEO of Kato Worldwide. Recently he published his new book entitled "Healing Civilizations: The Search for Therapeutic Essential Oils and Nutrients" Cameron Books, Petaluma, CA.

Association Activities

Meanwhile, measures to confront this negative publicity include the efforts of the Personal Care Product Council (PCPC) to rally the industry to pool their resources and produce the necessary data (MUsT and DART tests) that would possibly vindicate a portion of Category III filters. PCPC targeted eight of the 12 UV filters proposed to be Category III by the FDA: avobenzone, oxybenzone, octinoxate, octocrylene, homosalate, octisalate, ensulizole and meradimate. In June, the Public Access to SunScreen (PASS) Coalition submitted a petition to FDA entitled "Sunscreen Drug Products for Over-the-Counter Human Use."[6] PASS supports the use of sunscreens as a key part of a comprehensive sun protection plan and advocates that Americans have access to safe and effective sunscreens. PASS urged the agency to ensure a balance between the risks and benefits of sunscreen use as it finalizes its proposed rule. This 12-page document also advocates having the FDA address numerous concerns voiced by consumers and urges the FDA to:

- Clarify that additional testing is being performed given the change in use and application frequency by consumers and not because there is a concern that the ingredients are now deemed to be unsafe.
- Consider a tentative GRASE finding with additional testing for the eight filters that the industry plans to support.
- Consider alternate testing regimes to determine absorption and health effects of these ingredients.
- Clarify how the FDA will make decisions about the status of existing sunscreen ingredients while manufacturers are testing them.

I do not subscribe to one position PASS advocated in its petition; namely its support for SPFs higher than 50. In its petition, PASS cites inconclusive evidence that SPF values over 60 can provide additional protections against sunburn and ultraviolet radiation as compared with lower SPF values! According to the American Academy of Dermatology, "there is not any scientific evidence that indicates using a sunscreen with an SPF higher than 50 can protect you better than a sunscreen with an SPF of 50."[7]

The FDA website listed all of the 1,577 comments received by the agency as of June 27, 2019. Many were written by ordinary Americans. A significant number of them objected to the use of animal testing. In fact, dozens used the same exact format of "I was shocked to learn that the FDA is proposing to require animal testing…" (obviously, a standard statement from an animal rights organization urging its members to write to FDA). Many others, supported by a Latino group, requested its members to write a cookie-cutter template"I must be able to trust my sunscreen products available on the market. In the past 20 years, melanoma has risen by 20% in the Latino community."

Combination Products

I submitted a petition to the FDA on June 25, 2019 concerning the FDA's Proposed Status of banning Sunscreen Insect Repellent Combination Products.[8] The petition addresses a particular combination involving the use of the EPA exempt on 25 (b) Actives list of essential oils/natural ingredients with proven insect-repellent properties,[9] with only the FDA Category I GRASE and EPA approved inorganic filter zinc oxide. The use of synthetic insect repellents DEET, IR3535, picaridin and permethrin are effective but, unfortunately, have a controversial record on both safety and potential interactions with the ultraviolet filter components of current combination products. Essential oils with proven effective insect repellent properties have been considered safe for thousands of years. Essential oils are used in medicinal therapy, well-being products, flavors for human consumption, fragrances for cosmetics and household products, and many other holistic and aromatherapeutic products. More importantly, no interactions between these essential oils and zinc oxide have ever been reported in the literature. Ease of application of a safe and effective single-use product will encourage the user to apply such products to prevent skin cancer and insect bite-related problems in one product. Consumer compliance with sun-protection measures is seriously lacking, and all measures to urge them to comply with convenient sun safety procedures must be encouraged.

In other news, two major symposia will be held in this Fall. The first is the bi-annual Florida Sunscreen Symposium in Orlando on Sep. 12-14th and the NYSCC Sunscreens and Antioxidant Symposium in New York on Nov. 13, 2019. I will be presenting in the NYSCC and chairing the technical session at the Florida Sunscreen Symposium. Both conferences feature very interesting speakers including Dr. Theresa Michelle, director of the FDA's Center for Drug Evaluation and Research, who will speak at the Symposium. As we await the FDA response to the submitted comments, I urge all concerned to participate in this very crucial period that will determine the future of sunscreen protection in the US. ●

References

1. https://floridianpress.com/2019/03/rooney-calls-to -protect-fl-coral-reefs/

2. US Virgin Island (https://abcnews.go.com/US/lawmakers-USvirgin-Islands-approve-bill-banning-sunscreen.

3. Murali K. Matta, David G. Strauss et al JAMA, May 6, 2019, "Effect of Sunscreen Application Under Maximal Use Conditions on Plasma Concentration of Sunscreen Active Ingredients.

4. https://www.silive.com/news/2019/06/schumer-calls-on-fda-to-test-all-sunscreen-ingredients-for-safety.html

5. http://times-herald.com/news/2019/06/isakson-other-senators-americans-need-more-sun-screen- education

6. Petition Concerning FDA's Proposed Status of Sunscreen-Insect-Repellent Combination Products (FDA tracking # 1k3-9apr-kgcy). https://www.regulations.gov/searchResults?rpp=25&po=0&s=1k3-9apr-kgcy&fp=true&ns=true

7. https://www.aad.org

8. Petition Concerning FDA's Proposed Status of Sunscreen-Insect-Repellent Combination Products (FDA tracking # 1k3-9aoe-lyl6). https://www.regulations.gov/searchResults?rpp=25&po=0&s=1k3-9aoe-lyl6&fp=true&ns=true

9. https://www.epa.gov/sites/production/files/2018-01/documents/minrisk-active-ingredients-tolerances-jan-2018.pdf